



Docket No.: 04305/100H942-US2
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Jens Holm et al.

Application No.: 10/001,245

Confirmation No.: 9286

Filed: November 15, 2001

Art Unit: 1644

For: NOVEL MUTANT ALLERGENS

Examiner: P. J. Nolan

PRE-APPEAL BRIEF REQUEST FOR REVIEW

MS AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

In accordance with the Pre-Appeal Brief Conference Program, Applicants hereby request a pre-appeal brief panel review of the final rejection mailed September 16, 2005 in the above-identified patent application.

The present Request is filed concurrent with the filing of a notice of appeal and before the filing of an appeal brief. No amendments are being filed with this request. A request for an extension of time and a check for the required fee are filed herewith, to extend the time to reply to the aforementioned final rejection to March 16, 2006.

Review is requested for the following reasons:

I. THE REJECTIONS UNDER 35 U.S.C. § 102 SHOULD BE WITHDRAWN BECAUSE THE REFERENCES CITED BY THE EXAMINER FAIL TO EXPLICITLY OR INHERENTLY DISCLOSE ANY MUTANT ALLERGEN HAVING AT LEAST FOUR PRIMARY MUTATIONS SPACED BY AT LEAST 15 Å AND THE INSTANT REJECTIONS DO NOT FALL WITHIN THE NARROW EXCEPTION WHEREIN A GENUS MAY SOMETIMES ANTICIPATE A SPECIES

[A] Introduction

Claims 1-22, 35, 64, and 66-82 stand provisionally rejected under section 102(e) as anticipated by co-pending application no. 10/719,553 (the '553 application), published as U.S. Publication No. 2004/0091500 and rejected under section 102(b) as anticipated by published international patent application WO 99/47680 (WO '680). The '553 application and WO

'680 are counterpart applications having the same disclosure. The bases of the respective rejections under 102(e) and 102(b) are thus identical, and are addressed here only once.

For Applicants' complete argument against the rejections under 102(e) and 102(b), the panel is referred to Applicants' Response to Final Office Action Under 37 CFR §1.116 that was filed on January 17, 2006 ("Response to Final Office Action"), Section II, pages 12-15 and Applicants' Response to Non-Final Office Action (37 CFR §1.111) that was filed July 5, 2005 ("Response to Non-Final Office Action"), Section III.A., pages 13-14 and Section III.C, page 14.

[B] The Cited Prior Art Does Not Disclose the Claimed Invention

Anticipation requires that every limitation of a rejected claim be set forth explicitly or inherently in a single reference. *Verdegaal Bros. v. Union Oil Co. of Calif.*, 814 F.2d 628, 631 (Fed. Cir. 1987). The proper test is whether "each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Constant v. Advanced Micro-Devices, Inc.*, 848 F.2d 1560, 1570 (Fed. Cir. 1988). All pending claims of the subject application call for a recombinant mutant allergen having at least four primary mutations. See, e.g., claim 1. Among other features called for in the claims, the four primary mutations are spaced from each other by at least 15 Å. *Id.* The references cited by the Examiner fail to explicitly disclose a recombinant mutant allergen comprising at least four mutations spaced from each other by at least 15 Å. Response to Final Office Action at page 13, lines 3-7. Nor do the references cited by the Examiner inherently disclose a recombinant mutant allergen comprising at least four mutations spaced from each other by at least 15 Å. *Id.* at page 13, lines 7-14. Thus, the references cited by the Examiner fail to disclose the claimed invention, either explicitly or inherently.

[C] The Examiner's Rationale for Rejecting the Claims as Anticipated by the Prior Art of Record Applies an Incorrect standard of Anticipation

The Examiner's rationale for rejecting the claims as anticipated under 102(e) by the '553 application is that the "['553] application discloses some of the same Bet v1 mutants, disclosed in the current application, for use in allergen therapy. See claim 26 in application 10/719,553 for example." Final Office Action mailed September 16, 2005 at page 2. Whether or not the instant application and the prior art "disclose some of the same Bet v1 mutants" is not the standard for anticipation. A prior art reference anticipates a claims only if it discloses the claimed invention. The presently claimed invention calls for a mutant allergen comprising at

least four mutations spaced from each other by at least 15 Å. The rationale offered by the Examiner improperly equates the list of primary mutations disclosed in the ‘553 application with the limitation of at least four mutations spaced from each other by at least 15 Å that is called for in the claims. Thus, the rationale offered for the 102(e) rejection does not meet the standard for anticipation.

[D] The Instant Rejections Do Not Fall Within the Narrow Exception Wherein a Genus May Anticipate a Species

In the absence of any disclosure in the cited references that explicitly or inherently discloses the limitation of four primary mutations spaced from each other by at least 15 Å, the Examiner cites general teachings found in the cited references and concludes that the one of ordinary skill in the art “using the teachings” of the prior art of record could “readily envisage” a mutant allergen with four primary mutations each of which is at least 15 Å apart. Final Office Action at page 3. Thus, the Examiner apparently attempts to invoke a narrow exception to the general rules for anticipation, whereby a chemical genus may anticipate a species “[i]f one of ordinary skill in the art is able to ‘at once envisage’ the specific compound within the generic formula.” MPEP§ 2131. 02, *citing In re Petering*, 301 F.2d 676, (CCPA 1962). *See* Response to Final Office Action at page 14. The Examiner apparently concludes that the genus of mutant allergens comprising at least four of the single mutations disclosed in the cited references anticipates the species that is a mutant allergen comprising four primary mutations spaced from each other by at least 15 Å. The Examiner’s conclusion fails, however, both in fact and at law.

The Examiner's conclusion fails in fact because the prior art of record does not include any teaching on the spacing of primary mutations that one of ordinary skill in the art could use to arrive at a mutant allergen comprising four primary mutations each of which is at least 15 Å apart. The Examiner does not point to any such teaching. None exists. The only disclosure the Examiner points to that teaches the claimed invention is found in the instant application, not the cited prior art. *See* Response to Final Office Action at page 15, lines 1-6. Thus, the Examiner is wrong to conclude that one of ordinary skill in the art could "[use] the teachings" of the cited references to arrive at the claimed invention.

The Examiner’s conclusion also fails at law. In a narrow exception to the general rules of anticipation, the disclosure of a “small genus” may anticipate a species that falls within the genus, even if the species is not specifically disclosed. *Bristol-Myers Squibb Co. v. Ben Venue Laboratories, Inc.*, 246 F.3d 1368, 1380 (Fed. Cir. 2001), citing *In re Petering*, 301 F.2d 676, 681-82 (CCPA 1962). In reaching its decision, the *in re Petering* court relied on a finding

that “the pattern of [the prior art’s] specific preferences in connection with [its] generic formula constitutes a description of a definite and limited class of compounds.” *In re Petering* at 681. The court concluded that upon reading the prior art, one of ordinary skill in the art could “at once envisage *each member*” of a “limited class.” *Id.*, emphasis in original. *See also In re Sivaramakrishnan*, 673 F.2d 1383 (CCPA 1982) (Species anticipated by genus where one of ordinary skill “informed by the teachings” of the prior art need not “choose judiciously from a genus of possible combinations” to arrive at the claimed invention.); *In re Schaumann*, 572 F.2d 312, 316-17 (CCPA 1978) (anticipation existed where prior art disclosure “led inevitably to the conclusion that the reference provides a description of those compounds just as surely as if they were identified in the reference by name).

The rejections under section 102 fail to meet the standard for the exception established by the *In re Petering* line of cases. The prior art of record fails to include any teaching or “pattern of preferences” that directs one of ordinary skill in the art to a mutant allergen comprising at least four primary mutations spaced from each other by at least 15 Å. To arrive at the claimed invention would require one of ordinary skill in the art to make a “judicious selection” from among the 1680 quadruple mutants that could be formed using the eight primary Bet v1 mutation that are disclosed in the prior art of record. *See* Response to Final Office Action at page 14-15. In view of the failure of any guidance or preferences in the cited references and the large number of possible quadruple mutants that could be formed from the primary mutations disclosed therein, the cited references fail to meet the legal standard that one of ordinary skill in the art be able to “at once envisage *each member*” of the limited class of quadruple mutants wherein the individual mutations are spaced from each other by at least 15 Å. Hence, the genus of a Bet v1 mutant comprising four or more of the individual mutations set forth in the prior art of record does not anticipate the claimed invention that calls for a mutant allergen comprising at least four mutations spaced from each other by at least 15 Å.

[E] Conclusion

For at least the reasons set forth above, the pending rejections under 35 U.S.C. §§ 102(b) and (e) should be withdrawn.

II. THE OBVIOUSNESS-TYPE DOUBLE PATENTING REJECTION SHOULD BE WITHDRAWN BECAUSE THE CLAIMS CITED BY THE EXAMINER FAIL TO SUGGEST THE CLAIMED INVENTION AND THERE IS NO REASONABLE EXPECTATION OF SUCCESS THAT THE CITED CLAIMS COULD BE MODIFIED TO ARRIVE AT THE CLAIMED INVENTION

Claims 1-22, 35, 64, and 66-82 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting over claims 36-96 of the ‘553 application.

Applicants note at the outset that because this is a “provisional” rejection, upon withdrawal of all other rejections, the instant rejection should be withdrawn and the claims be allowed. Thus, Applicants are not required to address the substance of the instant rejection in order to obtain allowance of the pending claims. In the interest of completeness and establishing a record that the instant rejection is improper, however, Applicants choose to address the substance of the obviousness-type double patenting rejection, as follows.

Applicants' previous arguments against the instant rejection are found in the Response to Final Office Action, Section III., pages 15-17, which is incorporated directly herein, by reference.

As set forth in full in the Response to Final Office Action, the obviousness-type double patenting rejection is improper because there is no suggestion which four (at least), if any, of the mutations set forth in the claims of the '553 application should be or could be combined to arrive at a mutant with at least four primary mutations spaced by at least 15 Å. *Id.* at page 16. Nor is there any reasonable expectation of success that four mutations in the '553 application claims could be combined to arrive at a mutant with at least four primary mutations spaced by at least 15 Å. *Id.* Rather than finding the motivation to modify the claims of the '553 application and the expectation that such a modification could be accomplished successfully in the prior art, the Examiner has improperly looked to the disclosure of the instant application for the motivation and expectation of success to arrive at the claimed invention. *Id.*

For at least the reasons set forth above and further set forth in the Response to Final Office Action, Section III., pages 15-17, the obviousness-type double patenting rejection should be withdrawn.

Dated: March 16, 2006

Respectfully submitted,

By Walter Bunker

Mitchell Bernstein, Ph.D.

Registration No.: 46,550

DARBY & DARBY P.C.

P.O. Box 5257

New York, New York 10150-5257

(212) 527-7700

(212) 527-7701 (Fax)

Attorneys/Agents For Applicant